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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,363	03/21/2002	Hiroko Matsunaga	NITT.0049	5840
38327	7590	10/08/2004	EXAMINER KIM, YOUNG J	
REED SMITH LLP 3110 FAIRVIEW PARK DRIVE, SUITE 1400 FALLS CHURCH, VA 22042			ART UNIT 1637	PAPER NUMBER
DATE MAILED: 10/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,363

Applicant(s)

MATSUNAGA ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12 and 31-34, drawn to an apparatus for gene examination comprising a plurality of reaction compartments.

Group II, claim(s) 13-18 and 36-38, drawn to a method of assaying for polynucleotides.

Group III, claim(s) 19-31 and 39-43, drawn to a sample preparation instrument.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 recites that the unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical feature, wherein the expression of “special technical features” shall mean those technical features that define a contribution of which each of the claimed inventions, “considered as a whole, *make over the prior art.*”

The special technical feature, which is a gene examination apparatus comprising multiple reaction compartments, is not novel as such feature is disclosed by Heller et al. (U.S. Patent No. 5,632,957, issued May 27, 1997, see Figure 3 and 6, for example) and Zanzucchi et al. (WO 96/15450, issued May 23, 1996, see Figure 7B and 10, for example).

As the application fails to achieve a unity of invention as defined in PCT Rule 13.2, the claims are restricted to the above groups.

Additionally, inventions covered by I and III further do not share a special technical feature in that the products have different physical structures.

Additionally, 37 CFR 1.475 (b), states that claims drawn to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

- (1) A product and a process of producing the product
- (2) A product and a process of using the product
- (3) A product, process of producing the product, and a process of using the product
- (4) A process and an apparatus or means to carryout the process
- (5) A product, a process of producing the product, and an apparatus of means to carryout the process.

An application containing claims to more or less than one of the “combinations of categories” of inventions set forth above, unity of invention might not be present. (MPEP 1850).

Inventions covered by Groups I and III are drawn to two different products and thus is drawn to more than a single category of invention defined as set for in 37 CFR 1.475(b) and

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therefore, the inventions have been determined to lack unity of invention in pursuant to 37 CFR 1.475(b).

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

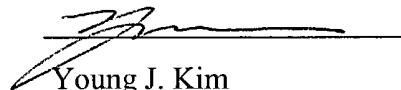
Finally Applicants are advised to amend the claims to prevent undue multiplicity of claims as defined in 37 CFR 1.75, wherein said rule states that, “more than one claim may be presented provided that they *differ substantially from each other and are not unduly multiplied.*” The claims of the instant application appears to recite claims which are substantially identical. Claims which are repetitious and multiplied results in confusion rather than clarification in defining an invention (MPEP 2173.05(n)).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The

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Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
10/1/04

YOUNG J. KIM
PATENT EXAMINER

yjk